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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/735,098

12/12/2003

Annika Margareta Pettersson-Fernholm

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05/18/2005

GLAXOSMITHKLINE

Corporate Intellectual Property - UW2220

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EXAMINER

GRASER, JENNIFER E

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/735,098	Applicant(s) PETTERSSON-FERNHOLM ET AL.	
	Examiner Jennifer E. Graser	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.  
 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 40-52 and 54-63 is/are pending in the application.  
     4a) Of the above claim(s) 40-52, 54 and 55 is/are withdrawn from consideration.  
 5) ☒ Claim(s) 56 and 57 is/are allowed.  
 6) ☒ Claim(s) 58-63 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.  
 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☒ Certified copies of the priority documents have been received in Application No. 09/485,760.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

S.O.D.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/6/05 has been entered.

Claims 40-52, 54, 55 and 56-63 are currently pending. Claims 40-52 and 54-55 were previously withdrawn from consideration as being drawn to a non-elected invention.

Claims 56-63 are currently under examination.

Note: support for the new limitation "at least 16 contiguous amino acids" is found on page 14, lines 5-8, in which it is recited fragments from about 1-20 and includes ranges larger or smaller by several, 5, 4 (i.e., 16), 3, 2 or 1.

### ***Specification***

2. The current status of all nonprovisional parent applications referenced at page 1, below the title, needs to be updated, e.g, Application Serial No. 09/485,760 is now abandoned.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 58-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Biswas et al (Infect. Immun. 1995. 63(8): 2958-2967).

Biswas et al teach isolated an polynucleotide which encodes a polypeptide which contains "at least 16 contiguous amino acids of the polypeptide of SEQ ID NO:2, 4, 6, 8 or 10". See attached sequence alignment. The open language "comprising" allows for polynucleotides which encode these polypeptides, plus much more (other amino acids) on either end of the contiguous match. The reference teaches the recombinant production of the polypeptide, which includes the use of a host cell and recombinant expression system. The kit of claim 63 only requires the isolated polynucleotide. Accordingly, the reference anticipates the kit. The term "kit" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

5. Claims 58 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Pettersson (Infect. Immun. 61(11): 4724-4733. 1993).

Pettersson et al teach an isolated an polynucleotide which encodes a polypeptide which contains "at least 16 contiguous amino acids of the polypeptide of SEQ ID NO:2, 4, 6, 8 or 10". See attached sequence alignment. The open language "comprising"

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allows for polynucleotides which encode these polypeptides, plus much more (other amino acids) on either end of the contiguous match.

6. Claims 58 -63 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al (FR 2692592) equivalent to US Patent No. 6,028,049.

Jacobs et al teach isolated an polynucleotide which encodes a polypeptide which contains "at least 16 contiguous amino acids of the polypeptide of SEQ ID NO:2, 4, 6, 8 or 10". See attached sequence alignment. The open language "comprising" allows for polynucleotides which encode these polypeptides, plus much more (other amino acids) on either end of the contiguous match. The reference teaches the recombinant production of the polypeptide, which includes the use of a host cell and recombinant expression system. The kit of claim 63 only requires the isolated polynucleotide. Accordingly, the reference anticipates the kit. The term "kit" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

7. Claims 58-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Pettersson et al (Microb. Pathog. 17(6): 395-408. 1994).

Pettersson al teach isolated an polynucleotide which encodes a polypeptide which contains "at least 16 contiguous amino acids of the polypeptide of SEQ ID NO:2, 4, 6, 8 or 10". See attached sequence alignment. The open language "comprising" allows for polynucleotides which encode these polypeptides, plus much more (other

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amino acids) on either end of the contiguous match. Pettersson et al teach an isolated polynucleotide which encodes a polypeptide comprising contiguous amino acids 559-774 of SEQ ID NO:6. The reference teaches the recombinant production of the polypeptide, which includes the use of a host cell and recombinant expression system. The kit of claim 63 only requires the isolated polynucleotide. Accordingly, the reference anticipates the kit. The term "kit" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

8. Claims 58 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Millet et al (WO 95/333049).

Millet et al teach isolated an polynucleotide which encodes a polypeptide which contains "at least 16 contiguous amino acids of the polypeptide of SEQ ID NO:2, 4, 6, 8 or 10". See attached sequence alignment. The open language "comprising" allows for polynucleotides which encode these polypeptides, plus much more (other amino acids) on either end of the contiguous match.

***Allowable Subject Matter***

9. Claims 56 and 57 are allowed. Claim 58 is not allowable. Claims 59-63 would be allowable if they were amended to solely depend from allowed claims 56 and/or 57.

**NOTE:** The prior art is replete with *numerous* prior art references that teach isolated polynucleotides which encode polypeptides of at least 16 (and many more)

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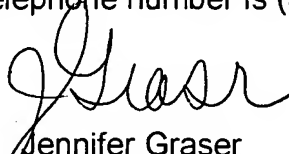
contiguous amino acids of SEQ ID Nos: 2, 4, 6, 8 or 10. It was not possible to list all of these prior art references. The prior art does not teach isolated polynucleotides which are at least 90% identical to SEQ ID NOs:1 (nucleotides 100-2274), 3, 5, 7 or 9. The problem with the claims drawn to this invention which were submitted on 12/10/14 was due to enablement since the specification does not teach which changes could be made to the sequences and still produce a functional polypeptide and the claims, themselves, required no function for the variant sequences. However, the specification does teach the use of isolated polynucleotides which are at least 90% identical to SEQ ID NOs:1 (nucleotides 100-2274), 3, 5, 7 or 9 which can detect *N.meningitidis* DNA through hybridization. Claims drafted in this manner would be allowable. Applicants are encouraged to call the Examiner to expedite the application.

10. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

 5/16/05  
Jennifer Graser  
Primary Examiner  
Art Unit 1645